

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

ABBVIE INC. et al.,

Defendants.

CIVIL ACTION

Case No. 14-cv-5151

**DEFENDANTS' OPPOSITION TO FTC'S MOTION TO COMPEL
DEFENDANTS TO "CORRECT DEFICIENT INTERROGATORY ANSWERS"**

TABLE OF CONTENTS

	Page
INTRODUCTION	1
ARGUMENT	2
I. The Facts Sought in Interrogatory No. 22 Are Irrelevant, But Defendants Properly and Fully Answered the Interrogatory Anyway.....	2
A. The Facts Sought in the Interrogatory Are Irrelevant and Not Proportional to the Needs of the Case.....	2
B. The FTC’s Request for Evidence Supporting the Facts That Defendants Identified Is Not Appropriate.....	4
C. The FTC’s Request That Defendants Explain When They Became Aware of the Identified Facts Is Also Improper	5
II. Interrogatory No. 23 Asked for Contentions on Irrelevant Issues	5
CONCLUSION.....	8

TABLE OF AUTHORITIES

Page(s)

CASES

<i>Atlas Powder Co. v. E.I. du Pont De Nemours & Co.</i> , 750 F.2d 1569 (Fed. Cir. 1984).....	2
<i>Commil USA, LLC v. Cisco Systems, Inc.</i> , 135 S. Ct. 1920 (2015).....	3
<i>Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.</i> , 535 U.S. 722 (2002).....	3
<i>Graham v. John Deere Co.</i> , 383 U.S. 1 (1966).....	2
<i>Insituform Technologies, Inc. v. Cat Contracting, Inc.</i> , 99 F.3d 1098 (Fed. Cir. 1996).....	6
<i>Pioneer Magnetics, Inc. v. Micro Linear Corp.</i> , 330 F.3d 1352 (Fed. Cir. 2003).....	7
<i>PSC Computer Products, Inc. v. Foxconn International, Inc.</i> , 355 F.3d 1353 (Fed. Cir. 2004).....	7
<i>Smith v. Café Asia</i> , 256 F.R.D. 247 (D.D.C. 2009).....	5
<i>Toro Co. v. White Consolidated Industries, Inc.</i> , 383 F.3d 1326 (Fed. Cir. 2004).....	6

FEDERAL STATUTES

35 U.S.C. § 103(a)	2, 3, 8
35 U.S.C. § 255.....	6
35 U.S.C. § 282.....	3

INTRODUCTION

The Court should deny the FTC's motion to compel additional answers to two interrogatories.

For interrogatory no. 22 to the AbbVie Defendants (interrogatory no. 15 to Besins), the motion is in reality a new set of interrogatories. The original interrogatory sought "all facts of which [Defendants] were aware as of December 21, 2001, or any time thereafter, regarding . . . secondary consideration[s] supporting non-obviousness" of certain testosterone gel compositions. As an initial matter, the facts sought in this interrogatory are irrelevant because "secondary considerations" are facts relating to patent validity, but the FTC has not put patent validity at issue in this case. Nevertheless, Defendants identified those facts; the FTC does not argue otherwise. The motion additionally seeks (1) an explanation of when the Defendants became aware of each identified fact, and (2) identification of the documents that support the identified facts. These are different questions that were not asked.

The only other interrogatory at issue, no. 23 to the AbbVie Defendants and no. 16 to Besins, is a contention interrogatory, asking whether Defendants contend that certain patent claims were drafted "inadvertent[ly]" or contained a "drafting error." Inadvertence or drafting errors are sometimes relevant in patent law, but they are not relevant to the FTC's claim here—and the FTC does not argue otherwise in its motion. Thus, Defendants do not have contentions, positive or negative, on the topic, and properly objected that the interrogatory improperly seeks factual contentions on irrelevant issues. Defendants also provided their actual contentions on both the law and the facts. Nothing more is required.

ARGUMENT

I. The Facts Sought in Interrogatory No. 22 Are Irrelevant, But Defendants Properly and Fully Answered the Interrogatory Anyway

A. The Facts Sought in the Interrogatory Are Irrelevant and Not Proportional to the Needs of the Case

Interrogatory no. 22 asked the AbbVie Defendants to “[i]dentify . . . facts” regarding “unexpected or unique pharmacokinetic or pharmacodynamic profile[s]” or “any other secondary consideration supporting non-obviousness” of certain types of testosterone gel compositions. Dkt. 188-7 at 13. The FTC propounded the same interrogatory to Besins as no. 15.

“Secondary considerations” are facts relevant to whether a patent would have been “obvious” to a person of ordinary skill in the art at the time of the invention—and thus invalid under 35 U.S.C. § 103(a). Taking “secondary considerations” into account helps to counter the tendency to let hindsight bias taint the determination whether a now-prevalent patented invention was obvious back at the time it was first invented. *See Graham v. John Deere Co.*, 383 U.S. 1, 36 (1966) (secondary considerations “guard against slipping into use of hindsight” in determining whether a patent would have been obvious at the time of the invention); *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1574 (Fed. Cir. 1984) (“‘[S]econdary’ considerations, when present, may assist the court in determining nonobviousness without falling prey to hindsight reasoning.”). For example, if a patented invention solved a problem that others previously had unsuccessfully tried to solve, then the others’ lack of success would be evidence that the patented invention was not obvious to those who were working in the same field at the same time. *Graham*, 383 U.S. at 17-18 (listing “failure of others” as an example of a secondary consideration of nonobviousness).

The facts sought in Interrogatory no. 22 are irrelevant because the FTC has not alleged that Defendants lacked a reasonable basis in the underlying litigations to assert that the ’894

patent was valid—whether based on the nonobviousness requirement or any other requirement. Thus, the FTC’s motion should be denied for the threshold reason that interrogatory no. 22 is not proportional to the needs of the case. Nor is it reasonably calculated to lead to the discovery of admissible evidence. The FTC’s “sham litigation” claim relates to whether it was objectively baseless for Defendants here to have argued that the doctrines of prosecution history estoppel and disclosure-dedication did not bar their argument that Perrigo’s and Teva’s generic versions of AndroGel 1% infringed the ’894 patent under the doctrine of equivalents. But while the FTC’s sham claim is premised on Defendants’ infringement allegations in the underlying patent litigations, nonobviousness relates to whether a patent is valid. *See* 35 U.S.C. § 103(a); *id.* § 282(a), (b)(2). And the FTC has not put the ’894 patent’s validity at issue. “[I]nfringement and validity are separate issues under the [Patent] Act.” *Commil USA, LLC v. Cisco Sys., Inc.*, 135 S. Ct. 1920, 1928 (2015).

The Supreme Court’s seminal decision on prosecution history estoppel, *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002), nowhere refers to secondary considerations of nonobviousness as being relevant to the analysis. In the meet-and-confer, Defendants asked the FTC to identify any judicial decision that the FTC believes links the two doctrines; the FTC provided none. Likewise, the FTC’s motion does not identify any judicial decision linking the two doctrines. In sum, the FTC propounded an interrogatory that has no relevance to its claims in the present litigation, as Defendants noted in their objections. On these grounds alone, the FTC’s motion should be denied.

B. The FTC's Request for Evidence Supporting the Facts That Defendants Identified Is Not Appropriate

Even though the facts requested in Interrogatory No. 22 are irrelevant, Defendants did not stand on their relevance objection. Instead, in response to the interrogatory, Defendants identified the requested facts:

- First, Defendants identified facts about the secondary consideration of whether the allegedly infringing products' result would have been "surprising and unexpected" at the time of the invention. The patented invention here, of which AndroGel 1% is an embodiment, produces steady blood levels of testosterone for a 24-hour period. That was surprising and unexpected when AndroGel 1% was invented, and Defendants identified the fact that it would have been surprising and unexpected to a person of ordinary skill in the art that some of the testosterone gel compositions at issue—such as the Teva and Perrigo testosterone gels—would produce steady blood levels of testosterone over a 24-hour period. Dkt. 188-7 at 14-15 (AbbVie Defendants); Dkt. 188-8 at 13 (Besins).
- Defendants also identified facts about other secondary considerations of nonobviousness. On the "long-felt need" secondary consideration, Defendants identified that at the time of the patented invention, the Teva and Perrigo testosterone gels would have solved (like AndroGel 1% in fact solved) a long-felt but unmet need for testosterone replacement therapy that produced steady blood levels of testosterone, did not subject patients to unnecessary pain, and did not have other undesirable administration requirements or side effects. Dkt. 188-7 at 15 (AbbVie Defendants); Dkt. 188-8 at 14 (Besins).
- Finally, Defendants identified facts about the "failure of others" secondary consideration. The responses identified other pharmaceutical companies (Cellegy, Macrochem, Schering, and Watson) that had tried to develop similar testosterone replacement therapies but failed in their efforts. Dkt. 188-7 at 15 (AbbVie Defendants); Dkt. 188-8 at 14 (Besins).

These are complete and proper responses to interrogatory no. 22 to the AbbVie Defendants and interrogatory no. 15 to Besins.

The first complaint in the FTC's motion is that Defendants' answers "provide no citations to documents or other evidence to substantiate the[] contentions." FTC Mem., Dkt. 188-1 at 4-5. But the interrogatory did not ask for any citations of documents or other supporting evidence. The interrogatory asked for Defendants to "[i]dentify . . . facts." Defendants provided facts.

“[A]n interrogatory asking for information about something and a request for [identification of] documents relating to the subject are two separate inquiries.” *Smith v. Café Asia*, 256 F.R.D. 247, 254 (D.D.C. 2009). There is no basis on which to compel Defendants to answer a further interrogatory that the FTC never served.

C. The FTC’s Request That Defendants Explain When They Became Aware of the Identified Facts Is Also Improper

The second complaint in the FTC’s motion is that Defendants’ answers “do not clarify whether Unimed and Besins were aware of data showing unexpected results for IPP or ISA at the time of the December 2001 supplemental amendment.” FTC Mem., Dkt. 188-1 at 5. Again, the interrogatory did not ask for that information, and a motion to compel is not a proper vehicle to pursue a follow-up interrogatory that was never propounded.

The only mention of dates in the interrogatory is the request that the facts to be provided be facts “of which You were aware as of December 21, 2001, or any time thereafter.” Dkt. 188-7 at 13; Dkt. 188-8 at 12. The facts provided are facts of which Defendants were “aware as of December 21, 2001, or any time thereafter.” The interrogatory did not ask Defendants to identify the particular date on which they became aware of each fact listed in the answers. There was nothing “evasive” or incomplete about Defendants’ not going beyond the scope of the interrogatory that was propounded.

II. Interrogatory No. 23 Asked for Contentions on Irrelevant Issues

Interrogatory no. 23 was a contention interrogatory. It asked whether Defendants contend that certain patent claims were drafted “inadvertent[ly]” or contained a “drafting error.” The FTC propounded the same interrogatory to Besins as no. 16.

In some aspects of patent law, actual inadvertence or drafting errors are relevant.¹ Here, Defendants' position is that they are not relevant, and Defendants therefore do not have contentions, positive or negative, on the topic of interrogatory 23.

The FTC's claim in this case is that Defendants' infringement lawsuits against Teva and Perrigo were "sham" because Defendants' infringement claims under the doctrine of equivalents purportedly could not overcome the prosecution history estoppel doctrine and the disclosure-dedication rule. Application of those doctrines turns on an objective evaluation of the public record from the perspective of a person of ordinary skill in the art, not what the inventors or the patent attorney subjectively may have intended or meant to do (which may also be protected from disclosure by the attorney-client privilege). See *Insituform Techs., Inc. v. Cat Contracting, Inc.*, 99 F.3d 1098, 1107-08 (Fed. Cir. 1996) ("[I]n an estoppel analysis, we do not look to the subjective intent of the applicant and what the applicant subjectively believed or intended that he or she was giving up to the public. Rather, the standard for determining what subject matter was surrendered is objective" (footnote omitted)); *Toro Co. v. White Consol. Indus., Inc.*, 383 F.3d 1326, 1331 (Fed. Cir. 2004) ("Nor does this court agree that intent plays any role in the [disclosure-dedication] rule. To the contrary, one of the advantages . . . is that it is a purely objective test. The patentee's subjective intent is irrelevant" (alterations and omission in original)). In other words, what matters is not what the patentee actually intended but what the public record would tell the public was intended.

In its motion, the FTC does not argue otherwise. According to the FTC's motion, the FTC propounded this interrogatory not because the FTC believes that these issues are relevant to

¹ For example, 35 U.S.C. § 255 allows the PTO to issue a certificate of correction to an issued patent that contains a "mistake of a clerical or typographical nature, or of minor character"—e.g., a drafting error.

its claim but because “[p]atentees in other doctrine of equivalents cases . . . have argued that the omission or exclusion of an alleged equivalent from an amended claim was inadvertent.” FTC Mem., Dkt. 188-1 at 5. The “other doctrine of equivalents cases” that the FTC appears to have in mind are *PSC Computer Products, Inc. v. Foxconn International, Inc.*, 355 F.3d 1353 (Fed. Cir. 2004), which involved the disclosure-dedication rule, and *Pioneer Magnetics, Inc. v. Micro Linear Corp.*, 330 F.3d 1352 (Fed. Cir. 2003), which involved the doctrine of prosecution history estoppel. *See* FTC Mem., Dkt. 188-1 at 5 n.11. These two cases confirm that any subjective intent in making an amendment—whether that subject intent would show actual inadvertence or error—would be irrelevant to the issues in this case; what matters is what the documents in the PTO’s patent file history show objectively.

The FTC argues in its motion to compel that interrogatory no. 23 “seeks to clarify whether Defendants will make similar arguments” to those rejected by the Federal Circuit. FTC Mem., Dkt. 188-1 at 5. But, once again, that is not the question that the FTC asked. Furthermore, Defendants made clear in the motion for summary judgment filed more than a year ago that the arguments that are the basis for the FTC’s claim in this case turn on an objective inquiry, not on Defendants’ actual subjective intent in amending the patent—whether that resulted in an inadvertent omission, a drafting error, or anything else. *See, e.g.*, Dkt. 59 at 28 (whether prosecution history estoppel bars infringement under the doctrine of equivalents “is an objective determination made based upon the information in the patent’s file history”); *id.* at 29 (describing the “objective evidence”). And in the meet-and-confer, Defendants have never suggested otherwise.

Furthermore, in response to the interrogatory, Defendants did not stand on their objections, but instead went on to provide a detailed statement of their substantive contentions—

both factual and legal—on the general issue of prosecution history estoppel. The AbbVie Defendants, for example, responded:

[T]he AbbVie Defendants respond that the applicability of prosecution history estoppel and the applicability of the disclosure-dedication rule are based on an objective evaluation of the public record from the perspective of a person of ordinary skill in the art, not the patentee's subjective reasons for drafting the claims. As the file wrapper of the '894 patent shows to a person of ordinary skill in the art, the amendment of October 19, 2001, was made in response to a rejection under 35 U.S.C. § 103(a) over certain prior art, principally Mak, that disclosed a transdermal testosterone formulation using oleic acid as the penetration enhancer. The examiner acknowledged that "[t]he prior art does not expressly disclose the employment of the particular penetration enhancer, isopropyl myristate," that is used in AndroGel, but stated that it would have been obvious to employ isopropyl myristate in a testosterone gel when Mak was considered in view of other prior art, Allen, because Allen disclosed isopropyl myristate to be "useful for facilitating the transdermal delivery of pharmaceuticals," in the context of an active ingredient that was not testosterone. In the amendment of October 19, 2001, the inventors argued that the examiner was unfounded in her prior conclusion that all penetration enhancers are equivalent and freely interchangeable regardless of the active ingredient in a particular drug, but did not make any arguments that were based on the dropping of isopropyl palmitate from the literal scope of the claims. Thus, based on the public record, including the file history, the objectively apparent reason isopropyl palmitate was not literally claimed in the claims proposed in the amendment of October 19, 2001, was not because the claims otherwise would have been obvious in view of the prior art. All of the inventors' arguments for patentability would have applied equally if isopropyl palmitate had been literally claimed in the claims proposed in the amendment of October 19, 2001. Based on the public record, a person of ordinary skill in the art would conclude that the rationale underlying the amendment of October 19, 2001, bears no more than a tangential relationship to isopropyl palmitate.

Dkt. 188-7 at 17-18 (citations omitted).

In short, Defendants have adequately stated their factual and legal contentions on the issue that seemed to be implicated by this interrogatory.

CONCLUSION

The motion should be denied.

Dated: July 14, 2016

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CERTIFICATE OF SERVICE

I certify that, on July 14, 2016, the foregoing document was filed with the United States District Court for the Eastern District of Pennsylvania using the ECF system. The document is available for viewing and downloading.

/s/ Adam R. Lawton